

Amendment and Response

Applicant: Jack D. Lemmon

Serial No.: 10/688,718

Filed: October 17, 2003

Docket No.: M190.143.101

Title: PROSTHETIC HEART VALVE SIZER ASSEMBLY WITH FLEXIBLE SIZER BODY

REMARKS

These remarks are made in response to the Final Office Action mailed August 24, 2005. In that Office Action, the Examiner rejected claims 1-6, 8-11, and 15-19 were rejected under 35 U.S.C. §102(b) as being anticipated by Buchanan, U.S. Patent Publication No. 2002/017384 ("Buchanan"). Claims 1-6, 8-10, 12, 13, 15-21, 25-28, and 30 were rejected under 35 U.S.C. §102(b) as being anticipated by Love et al., U.S. Patent Publication No. 2002/0020074 ("Love"). Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Love. Claims 1-6, 8-13, 15-21, 25-28, and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Rhee, U.S. Patent No. 6,350,281 ("Rhee") in view of Love.

The Examiner's indication that claim 38 has been allowed is noted with appreciation. Further, the Examiner's indication that claims 22-24, although objected to as being dependent upon a rejected base claim, would be allowable if re-written is also noted with appreciation.

With this Response, claims 1 and 20 have been amended, and new claim 39 added. Claims 1-31, 38, and 39 are pending in the application and are presented for consideration and allowance.

Claim 1 has been amended to recite that the flexible sizer body includes a continuous outer ring that defines an undulating, contoured end surface of the sizer body. Support for this language is found, for example, in FIG. 8 and page 8, line 23 – page 9, line 2. With respect to the rejection of claim 1 based on Buchanan, it is respectfully noted at the outset that Buchanan describes a prosthetic heart valve and not a flexible sizer body. Similar to other heart valve prostheses, the prosthetic heart valve of Buchanan includes a stent 40 supporting three leaflets 42. The leaflets 42 extend through slits 18 in the stent 10 and are individually wrapped onto themselves to form separate attachment portions 44 that in turn serve as sewing or suture cuffs (Buchanan, para. 17; FIG. 2A). The separately-formed attachment portions 44 are not connected to one another (as shown in FIG. 2A) such that a continuous outer ring as set forth in amended claim 1 does not exist. For at least this reason, then, amended claim 1 is novel over Buchanan. Further, because Buchanan is specifically directed toward a prosthetic heart valve and not a flexible sizer body, it is respectfully submitted that Buchanan is not analogous art, and thus

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unavailable for use as part of an obviousness rejection. Thus, it is respectfully submitted that amended claim 1, and all claims depending therefrom, is allowable over Buchanan.

With respect to the rejection of claim 1 based on Love, the circular sizing portion 1 (analogized by the Examiner as being the “outer ring” of claim 1) is a continuous circle or right cylinder. Thus, Love does not teach or suggest an outer ring defining an undulating, contoured end surface of the sizer body as otherwise set forth in amended claim 1. Thus, for at least these reasons, then, it is respectfully submitted, and all claims depending therefrom, is allowable over Love.

With respect to the rejections of claim 1 based upon Rhee in view of Love, Applicant respectfully disputes the asserted suggestion identified in the Office Action for modifying Rhee in view of Love. The sizer 10 of Rhee includes a support member 14 and a resilient member 16. The support member 14 forms a body 18 and a retainer 20 within which the resilient member 16 is received, with the body 18 defining a distal portion of the sizer 10. As shown in the various figures of Rhee, the distal body 18 is a simple, continuous, right cylinder. This limited teaching is not surprising given Rhee’s focus upon using only the resilient member 16 (and not the distal body 18, otherwise analogized by the Examiner as being the claimed “annular wall”) to measure a size of the annulus 54 in question. More particularly, Rhee describes inserting the distal body 18 through the valve annulus 54 until the resilient member 16 abuts the valve annulus 54. Based upon a determination as to whether the resilient member 16 conforms to the valve annulus 54, a surgeon is able to select a properly-sized replacement valve. That is to say, Rhee does not teach or suggest the distal body 18 performing or providing any “sizing” or “evaluating” information; to the contrary, the distal body 18 exists simply for providing an initial guide structure to be inserted through the annulus 54. Because Rhee does not recognize the distal body 18 as providing any valve evaluation attribute, one of skill in the art upon reading Rhee would see no reason to modify or change the right cylindrical shape described, as any such modification would likely impede the ability of the distal body 18 to be simply inserted through the valve annulus 54. Pointedly, the language of Rhee referenced in the Office Action (col. 4, ll. 1-4) is specifically related to the configuration of the resilient member as “mimicking” an artificial heart valve and

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not the distal body portion. As such, it is respectfully submitted that claim 1 is not made obvious by Rhee in view of Love.

In addition, amended claim 1 recites that the outer ring defines an undulating, contoured end surface of the sizer body. In contrast, in each and every embodiment of Rhee, the resilient member 16 (that might otherwise be undulating) is offset from the ends of the sizer 10. In fact, because the support member 14 of Rhee must be configured to form a slot (the annular recess 22), it is impossible for the Rhee design to position the resilient member 16 so as to define the end surface of the sizer body. For at least this additional reason, then, it is respectfully submitted that amended claim 1, and all claims depending therefrom, is not made obvious by Rhee in view of Love.

In light of the above, it is respectfully submitted that amended claim 1, and claims 2-6, 8-13, and 15-19 depending therefrom, are allowable over the cited references.

Claim 20 has been amended to recite that the extremities define a proximal side of the sizer body, and that the handle extends proximally from the sizer body. With this configuration, a longitudinal length between the extremities and the second end of the handle is less than a longitudinal length between the outer ring and the second end of the handle. Support for this language is found, for example, in FIGS. 4 and 8. With respect to the rejection of claim 10 based on Love, Love describes the curved legs 2 as including a proximal end 2a and a distal end 2b. (Love, para. 18). With these conventions in mind, then, the ring 1 extends proximally from the legs 2, such that the curved legs 2 (and thus the “extremities” identified by the Examiner) define the distal side of the sizer, in contrast to amended claim 20. Further, the socket 4 is positioned such that the handle (not shown) extends proximally from the ring 1. Thus, a longitudinal length between an opposite end of the handle relative to the legs 2 is greater than a longitudinal length between the opposing handle end and the ring 1, again, in direct contrast to amended claim 20. This relationship is further supported by the discussion in Love relative to FIGS. 3-5 in which the handle 10 extends proximally from a base of the legs 16, 18. As such, it is respectfully submitted that amended claim 20, and all claims depending therefrom, are not made obvious by Love.

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With respect to the rejection of claim 20 based on Rhee in view of Love, Rhee similarly teaches (e.g., FIG. 1) that the handle 12 extends proximally from the ring 16, such that the distal body 18 extends in a direction opposite that of the handle. In other words, were Rhee modified such that the distal body 18 formed a plurality of extremities, these extremities would be positioned at a longitudinal length (relative to an opposing end of the handle 12) that is greater than a longitudinal length between the resilient member 16 and the opposing end of the handle. Thus, it is respectfully submitted that amended claim 20, and all claims depending therefrom, are allowable over Rhee in view of Love. In light of the above, it is respectfully submitted that amended claim 20, as well as claims 21 and 25-28 depending therefrom, are allowable over the cited references.

Newly presented claim 39 recites a prosthetic heart valve in combination with a flexible sizer body. The prosthetic heart valve includes a stent forming a stent ring and stent posts. A covering encompasses the stent, with the two components combining to define an annular extension. A sewing ring extends about the stent ring. Finally, a plurality of leaflets are provided, individual ones of which are secured between a respective pair of the stent posts. The annular extension and the sewing ring are characterized by differing flexibilities. The flexible sizer body is configured in tandem with the prosthetic heart valve and includes an outer ring and an annular wall. The outer ring has a flexibility approximating the flexibility of the sewing ring. The annular wall forms a plurality of extremities corresponding in shape and size with the plurality of stent posts. Further, the annular wall has a flexibility approximating that of the annular extension. Finally, the prosthetic heart valve and the flexible sizer body are comprised of differing materials. Support for this language is found, for example, at page 7, line 5 – page 10, line 19. In contrast, none of the cited references teach or suggest a prosthetic heart valve and a flexible sizer body formed in tandem. For example, the sizer of Love is provided to assess the geometry of a heart valve annulus for subsequent reconstruction; Love does not teach or suggest implantation of a prosthetic heart valve, let alone that the sizer is configured in tandem with a specific prosthetic heart valve. Similarly, while Rhee does relate to prosthetic heart valve applications, Rhee does not teach that the sizer 10 is configured in tandem with a specific prosthetic heart valve. Instead, the sizer of Rhee employs a resilient member 16 that represents

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the diameter of a generic prosthetic heart valve. That is to say, Rhee does not match the sizer 10 with a specific prosthetic heart valve; nor could it, as the distal body 18 has no relationship with the size and shape of an actual prosthetic heart valve.

For at least the above reasons, then, it is respectfully submitted that newly presented claim 39 is allowable over the cited references.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-31, 38, and 39 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-31, 38, and 39 is respectfully requested.

Applicants hereby authorize the Commissioner for Patents to charge Deposit Account No. 50-0471 the amount of \$200.00 (to cover the additional independent claim fee as set forth under 37 C.F.R. 1.16(h)).

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

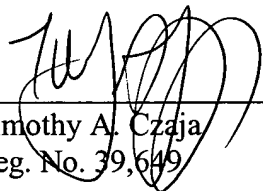
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CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope, address to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450 on this 23rd day of November, 2005.

By: 

Name: Timothy A. Czaja